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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,443	07/16/2003	Francesco Visinoni	00366.000183	6949

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NEW YORK, NY 10112

EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/619,443	Applicant(s) VISINONI, FRANCESCO	
	Examiner Frederick Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/22/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 10-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/2/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Restriction Requirement

Applicant's election without traverse of Group I in the reply filed on 02/22/07 is acknowledged.

Claims 10-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claim 1, the line of demarcation between components "(v)" and 1,2-propanediol (component "(iii)") is unclear, insofar as 1,2-propanediol is itself a monomeric polyhydroxy compound.

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2) Where values can vary depending on the basis for their determination, the claimed subject matter may be indefinite. *See Honeywell Intl. v. Intl. Trade Commn.*, 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it). Accordingly, the percent values recited by instant claims 5-7 are incomplete insofar as they do not specify the frame of reference used to measure them, e.g., percent by weight based on the weight of water, percent by weight based on the weight of the fixative composition, etc.

In order to overcome this ground of rejection the examiner recommends inserting a) the phrase “, based on the weight of the fixative composition” after the percent sign in claims 5 and 7, and b) the phrase “, wherein all percentages are based on the weight of the fixative composition” immediately before “respectively” in claim 6.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegfried et al (USP 4,946,669) in view of Slifkin (USP 5,508,175).

The primary reference discloses fixatives comprising water, 20 to 80 percent by weight concentrated (70 to 90%) ethanol, 15 to 70 percent propylene glycol, and an osmotic agent, e.g., a sugar such as glucose.¹ Other additives include salts and acids. See the passage bridging column 2, line 29 to column 3, line 10. The primary reference

¹ One skilled in the art will appreciate that the prior art term "propylene glycol" is equivalent to applicant's recitation of "1,2-propanediol", since it is well known that propylene glycol is provided commercially available as in the form of its 1,2-isomer. See USP 7,084,310.

differs from the instant claims in its silence regarding poly vinyl alcohol.²

The secondary references teaches the use of 2-6 percent poly vinyl alcohol in 70 percent ethanol (column 3, lines 54-56) as an adhesive for fixative specimens (first paragraph of column 2). The prior art is silent regarding propylene glycol.

Generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. See Sinclair & Carroll Co. v. Interchemical Corp., 325 US 327, 65 USPQ 297 (1945). See also In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Accordingly, it would have been obvious to have incorporated polyvinyl alcohol into the fixatives of the primary reference, motivated by the desire to impart the art-recognized adhesive properties of polyvinyl alcohol thereto, consonant with the reasoning of the cited precedent.

2) Claim 4 is rejected under 35 USC 103(a) as being unpatentable over Siegfried et al (USP 4,946,669) in view of Aung et al (USP 5,338,558).

The primary reference is discussed supra and differs from the instant claim insofar as it does not specify the use of a hexitol, e.g., sorbitol. It does clearly suggest the use of osmotic agents generally, however, in its use of the qualifiers “such as” and “the like” at column 2, lines 54 and 55.

The secondary reference teaches that sorbitol is a known osmotic agent for use in

² The prior art also differs from instant claim 5 insofar as it does not specify the percentage of osmotic agent used. Generally, however, it is prima facie obvious to determine workable or optimal values within a prior art disclosure through the application of routine experimentation. See In re Aller, 105 USPQ 233, 235 (CCPA 1955); In re Boesch, 205 USPQ 215 (CCPA 1980); and In re Peterson, 65 USPQ2d 1379 (Fed. Cir. 2003). Since other useful osmotic agents disclosed include sodium chloride, which would be used in only

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dehydrating preservatives (fixatives). It differs from the instant claims insofar as it is silent regarding ethanol-based systems.

It would have been obvious to have used a hexitol as an osmotic agent in the primary reference, motivated by the recognition that same are known osmotic agents as illustrated by the secondary reference, consonant with the reasoning of the previously cited Sinclair and Leshin decisions.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'F. Krass', written over the printed name.